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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,441	12/08/2003	Rajeeva Singh	A8689	3309

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EXAMINER	
DUFFY, BRADLEY	
ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/729,441	SINGH ET AL.	
	Examiner	Art Unit	
	BRADLEY DUFFY	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8, 11, 14-22 and 24-72* is/are pending in the application.

4a) Of the above claim(s) *20,21,25,28,29,35,36,52-58,64-66 and 70-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,11,14-19,22,24,26,27,30-34,37-51,59-63 and 67-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/12/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed December 12, 2008, is acknowledged and has been entered. Claims 8, 11, 14-21, 24, 25, 33 and 37 have been amended. Claims 1-7, 9, 10, 12 and 13 have been canceled. Claims 38-72 have been newly added.

2. The amendment filed March 18, 2009, is acknowledged and has been entered. Claims 8, 11, 14-16, 35-36, 38-43, 59-60 and 64-72 have been amended.

3. Claims 8, 11, 14-22 and 24-72 are pending in the application.

4. Claims 20, 21, 25, 28, 29, 35, 36, 52-58, 64-66 and 70-72 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

5. Claims 8, 11, 14-19, 22, 24, 26, 27, 30-34, 37-51, 59-63 and 67-69 are under examination.

Election/Restriction

6. The amendment filed December 12, 2008, presents new claims 52-58, 64-66 and 70-72 and claims 68 and 69, in part, so as to be drawn to a non-elected invention.

These claims, as newly presented are directed to inventions that are independent or distinct from the inventions originally presented for the following reasons:

As a first point, new claim 52-56, are directed to the non-elected and non-rejoined invention of Group III as set forth in the restriction requirement mailed August 7, 2006 and have been withdrawn for this reason.

Secondly, the invention of new claims 57 and 58, which are drawn to new methods that recite diagnosing a subject suspect of having a cancer, said methods comprising administering to said subject an isolated antibody or fragment thereof,

wherein said antibody or said fragment comprises at least one heavy chain variable region and at least one light chain variable region, wherein said heavy chain variable region comprises three complementarity-determining regions comprising the amino acid sequences of SEQ ID NOS: 1-3, and wherein said light chain variable region comprises three complementarity-determining regions comprising the amino acid sequences of SEQ ID NOS:4-6, and wherein said antibody or said fragment specifically binds to IGF-IR; and, wherein said antibody or antibody fragment is labeled with a detectable moiety; and detecting the distribution of said reagent within said subject, is patentably distinct from the inventions previously presented because e.g., while this new invention is related to the previously examined product as a process of use, the labeled antibody could be used in the materially distinct process of e.g., purifying the antigen bound by the antibody. Furthermore, while the method of Group II has been rejoined with the elected invention (see office action mailed 11/6/06, page 2), the newly presented method of claims 57-58 is a materially different processes comprising different method objectives, process steps, reagents used and/or endpoints from the method of Group II. For example, the newly presented method requires administering to a subject an isolated antibody or fragment thereof, wherein said antibody or said fragment comprises at least one heavy chain variable region and at least one light chain variable region, wherein said heavy chain variable region comprises three complementarity-determining regions comprising the amino acid sequences of SEQ ID NOS: 1-3, and wherein said light chain variable region comprises three complementarity-determining regions comprising the amino acid sequences of SEQ ID NOS:4-6, and wherein said antibody or said fragment specifically binds to IGF-IR; and, wherein said antibody or antibody fragment is labeled with a detectable moiety; and detecting the distribution of said reagent within said subject, which is not required by Group II, which instead requires contacting a cell with a composition comprising an antibody or fragment thereof, wherein said antibody or said fragment comprises at least one heavy chain variable region and at least one light chain variable region, wherein said heavy chain variable region comprises three complementarity-determining regions comprising the amino acid

sequences of SEQ ID NOS:1-3; and wherein said light chain variable region comprises three complementarity-determining regions comprising the amino acid sequences of SEQ ID NOS:4-6: and a therapeutic agent. Therefore the invention set forth in new claims 57-58 is a materially distinct process as compared to Group II comprising different method objectives, process steps, reagents used and/or endpoints and claims 57-58 have been withdrawn for this reason.

Finally with respect to new claims 64-66 and 70-72 and claims 68 and 69, in part, these claims are directed to products that are antibodies comprising amino acid sequences having different amino acid sequences as compared to the amino acid sequences of the antibodies originally presented and examined. Notably, the originally presented and examined claims set forth antibodies that recited heavy chain variable regions having three complementarity-determining regions comprising the amino acid sequences of SEQ ID NOS: 1-3, and light chain variable regions having three complementarity-determining regions comprising the amino acid sequences of SEQ ID NOS:4-6 (see e.g., originally examined claim 7 as presented in the amendment filed 9/7/06), and further recited heavy chain amino acid sequences of SEQ ID NO:7 and 13 and light chain amino acid sequences of SEQ ID NO:8, 9, 10, 11 and 12 (see e.g., originally examined claims 11, 15 and 16 as presented in the amendment filed 9/7/06), while the newly presently claims recite an antibody having a heavy chain variable region comprising three complementarity-determining regions comprising the amino acid sequences of SEQ ID NOs: 1, ***54*** and 3, and a light chain variable region comprising three complementarity-determining regions comprising the amino acid sequences of SEQ ID NOs:4-6 (see claim 64); and further recite heavy chain amino acid sequences of SEQ ID NO:39, 40, 41, 42, 43, 44, 87 and 88 and light chain amino acid sequences of SEQ ID NO:53, 54, 55, 84, 85 and 86 (see claims 65-66 and 68-69).

In this case, the newly presented antibodies are patentably distinct, from the originally presented and examined antibodies, because while each is an antibody that comprises two light chains and two heavy chains, each are disclosed as comprising different amino acid sequences and/or different antigen-binding domains as compared

to the originally presented and examined antibodies. Accordingly, these newly claimed products, which now comprise different amino acid sequences, as compared to the antibody products to which the originally presented claims were directed, are structurally and functionally different products from the products which were elected by original presentation and examined because of these amino acid differences and because these antibodies which now comprise different amino acid sequences as compared to the antibody products as originally presented do not appear to be obvious variants of the originally presented subject matter based on the current record.

Secondly, the Examiner recognizes that, according to M.P.E.P § 803, there are two separate requirements that must be met to establish the propriety of the restriction between any two inventions. Having shown that the claims, as would be amended, are drawn to inventions patentably distinct from the elected invention, it is now necessary to provide reasons that there would be a serious burden on the examiner, to search and consider the claims as would be amended.

A serious search and examination burden exists if one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

In this case, there would be a serious search and consideration burden to consider the claims, as would be amended. Notably, the breadth of the claims, as

would be amended, differs so substantially from the breath of the originally presented claims, that examination of the amended claims would require new and different considerations and searches, which were not before necessary. For example, perhaps first and foremost, it is aptly noted that the inventions presented in the claims, as newly presented, require a different field of search than the claims as originally presented because different and distinct amino acid sequences would now have be searched and for the newly presented methods of diagnosing different text searches and classification searches would now be necessary. Notably, with particular regard to the newly presented antibodies comprising sequences that have not been previously searched, different sequence searches in up to 10 different databases would now be required to consider each antibody which presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the Examiner.

Accordingly, for these reasons, there would be a serious search and consideration burden to consider the claims, as newly presented.

Thus, if the newly presented claims had been originally presented, they would have been properly restricted from the inventions of the claims that were constructively elected by original presentation as such newly presented antibody products and methods have been shown to be patentably distinct from the originally presented and examined antibodies and method and because the examination of the claims, as would be amended, could not be made without serious burden. See MPEP § 803.

Accordingly, in order to clarify the record, the claims have been examined only insofar as the claims are drawn to the generic invention or to compositions comprising antibodies comprising the amino acid sequences originally presented and examined, i.e., SEQ ID NOs: 1-6 (see e.g., originally examined claim 7 as presented in the amendment filed 9/7/06), and SEQ ID NOs:7-13 (see e.g., originally examined claims 11, 15 and 16 as presented in the amendment filed 9/7/06). Again, this is because these were the antibodies to which the originally presented claims were drawn and because any other antibodies, which differ structurally and/or functionally from these

antibodies, are patentably distinct from those antibodies originally claimed, and could not be search or considered without a serious burden.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 52-58, 64-66 and 70-72 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

7. The references cited in the information disclosure statement filed on December 12, 2008, have been considered.

Priority

8. With regard to the issue of priority at page 17 of the response filed Applicant has disagreed with the Examiner's position that claims 8, 11, 14-19, 22, 24, 26, 27, 30-34, 37, 39-43, 59-60 and 62 do not properly benefit under 35 U.S.C. §§ 119 and/or 120 by the earlier filing dates of the priority documents claimed, submitting that the instant claims are adequately enabled and have adequate written description.

In response, after careful and complete consideration, this argument is not found persuasive for claims 8, 11, 14-19, 22, 24, 26, 27, 30-34, 37, 39-43, 59-60 and 62 because they remain rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and a sufficiently enabling disclosure for the reasons set forth below.

Furthermore, Applicant appears to be arguing that claims 17, 30, and 32-34 benefit by the earlier filing date of the priority application because the priority document "describes a composition comprising an antibody and a second agent" and the priority document incorporates the second agents set forth in claims 17, 30, and 32-34 by reference, in view of Applicant's arguments relating to the incorporation by reference of these agents in the instant application.

In response, this argument is not found persuasive because the priority document is a CIP and whether the instant application properly incorporates these agents by reference is irrelevant to the disclosure of the priority document because the disclosure of this priority document is different and no support for these agents could be found in the document. In this case, Applicant has presented no evidence that the priority document incorporates these particular agents by reference and the Examiner could find no evidence supporting such an allegation in the priority document. If it is Applicant's position that each of the agents set forth in claims 17, 30, and 32-34 has been properly incorporated by reference in the priority document, Applicant is invited to identify in the priority document, i.e., CIP application 10/170,390, the passages where each of these agents are incorporated by reference and identify where in the references that have been properly incorporated by reference, these agents are disclosed as well as provide any reference that is not currently of record. Once again, Applicant's argument is not persuasive because although the document describes a composition comprising an antibody and a second agent, it does not describe such a composition comprising any of the agents of claims 17, 30, and 32-34, *per se* and because Applicant has not provided any evidence that these agents have been properly incorporated by reference in the priority document.

Accordingly, the effective filing date of claims 8, 11, 14-19, 22, 24, 26, 27, 30-34, 37, 39-43, 59-60 and 62 is deemed the filing date of the instant application, namely December 8, 2003.

Grounds of Objection and Rejection Withdrawn

9. Unless specifically reiterated below, Applicant's amendment and/or arguments filed December 12, 2008, have obviated or rendered moot the grounds of objection and rejection set forth in the previous Office action mailed June 13, 2008.

Notably, in order to clarify the record the prior art rejections are not being applied to new claims 59 and 60 because they recite an antibody "devoid of agonist activity" as

opposed to "substantially devoid of agonist activity", and the antibodies of the prior art were taught to have some agonist activity.

Grounds of Objection Maintained

Specification

10. The objection to the amendment filed April 16, 2007 under 35 U.S.C. 132(a) because it introduces new matter into the disclosure, is maintained. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention, is maintained. The added material which is not supported by the original disclosure is as follows: the paragraphs added after paragraph 92 from the DeVita et al reference that occurs on pages 2-9 of the amendment.

In the response filed December 12, 2008, Applicant has traversed this objection and reiterated that the Office's position is contrary to 37 CFR 1.57 and that the facts in *Ex parte Maziere* support that these agents have been properly incorporated and further points to the facts in *Southern Clay Products, Inc., v. United Catalysts, Inc., 43 Fed.Appx. 379, 64 U.S.P.Q.2d 1606 (Unpublished) (No. 01-1382) (July 26, 2002)* and the holdings in *In the Matter of the APPLICATION of Raymond O. VOSS*, as supporting that the incorporation by reference is proper.

In response, while the Examiner acknowledges the holdings of *Ex parte Maziere, Southern Clay Products, Inc., v. United Catalysts, Inc., 43 Fed.Appx. 379, 64 U.S.P.Q.2d 1606 (Unpublished) (No. 01-1382) (July 26, 2002)* and the holdings in *In the Matter of the APPLICATION of Raymond O. VOSS* pointed to by the Applicant, each case must be decided on its own facts.

As set forth by 37 CFR 1.57 (c): "Essential material" may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference.

Accordingly, while the holdings cited by Applicant refer to "Essential material" that was incorporated by reference to a U.S. patent or U.S. patent application

publication, this case differs because it incorporates non-patent literature, for example, and it is not apparent that these holdings apply in this case because "Essential material" may only be incorporated by reference to a U.S. patent or U.S. patent application publication.

Furthermore, while Applicant argues that the incorporation by reference of these particular second agents is proper, the instant issue is whether amending the specification to **include** certain sections of a non-patent literature document, while **excluding** other sections adds new matter to the specification.

In regard to this issue, it appears Applicant is arguing that the amendment filed April 16, 2007, does not add new matter because M.P.E.P. § 2163.07(b) sets forth that parts of a document may be incorporated by reference.

In this case, as set forth by Applicant's response, the DeVita reference at issue is referred to in the following contexts in the specification:

> [0094] The therapeutic agents that can be combined with EM 164 for improved anti-cancer efficacy include diverse agents used in oncology practice (Reference: Cancer, Principles & Practice of Oncology, DeVita, V. T., Hellman, S., Rosenberg, S. A., 6th edition, Lippincott-Raven, Philadelphia, 2001) …
>
> [0148] For these combination therapies, EM 164 is combined with one or more anti-cancer agents of diverse mechanisms of action such as alkylating agents, platinum agents, hormonal therapies, antimetabolites, topoisomerase inhibitors, antimicrotubule agents, differentiation agents, antiangiogenic or antivascularization therapies, radiation therapy, agonists and antagonists of leuteinizing hormone releasing hormone (LHRH) or gonadotropin-releasing hormone (GnRH), inhibitory antibodies or small molecule inhibitors against cell-surface receptors, and other chemotherapeutic agents (Reference: Cancer, Principles & Practice of Oncology, DeVita, V. T., Hellman, S., Rosenberg, S. A., 6th edition, Lippincott-Raven, Philadelphia, 2001).

Notably, both disclosures refer to anti-cancer properties of agents disclosed by Devita, while some of the agents which have been added to the specification do **not** have anti-cancer properties[1] and therefore, it is submitted that the amendment which

[1] For example, with respect to erythropoietin DeVita et al disclose that it is used to treat anemia (see page 2644), while pamidronate is used to treat bone pain (see page 2831).

only includes the portions of Devita et al disclosing thalidomide, carmustine, pamidronate, prednisone, erythropoietin and bisohosphonate, while excluding all the other disclosures of Devita et al referring to agents with anti-cancer properties constitutes new matter.

Accordingly, it is submitted that while parts of a document may be incorporated by reference if those parts are identifies with particularity, in this case the amendment constitutes new matter because the specification does not identify with any *particularity* the parts of DeVita that recite the thalidomide, carmustine, pamidronate, prednisone, erythropoietin and bisohosphonate agents in the specification as *originally filed*. As set forth by the CCPA in *In re Seversky,* 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"). Similarly, in *In re Saunders*, 444 F.2d 599, 602-03, 170 USPQ 213, 216-17 (CCPA 1971) the CCPA held that a reference only discloses information from an incorporated reference when it "expressly incorporates a particular part" of another reference.

In this case, the mere references to Devita et al in the specification which disclose anti-cancer agents would not have led one of skill in the art to understand that Applicant intended to specifically only include the portions of Devita et al disclosing thalidomide, carmustine, pamidronate, prednisone, erythropoietin and bisohosphonate, while excluding all the other disclosures of Devita et al. For this reason this position in not contradictory to 37 CFR 1.57.

Thus, after a careful and full consideration of Applicant's arguments, it is maintained that the specification amendment adds new mater to the disclosure.

Applicant is invited to provide appropriate rebuttal or cancel the new matter in the reply to this Office Action.

Claims

11. The objection to claims 22, 30, 31 and 34, as being drawn in the alternative to the non-elected invention of Group III, is maintained. Applicant has requested rejoinder

of the non-elected claims of Group III, upon allowance of product claims in the response to the restriction requirement filed September 9, 2006.

Grounds of Rejection Maintained

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. The rejection of claims 8, 11, 14-19, 22, 24, 26, 27, 30-34, 37, 39-43, 59-60 and 62 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

Starting at page 22 of the amendment filed December 12, 2008, Applicant has traversed the propriety of this ground of rejection.

Applicant's arguments have been carefully considered but are not found persuasive for the following reasons:

Again, the considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, ``Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001; hereafter "Guidelines"). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

As currently presented, the claims are directed to a structurally and functionally diverse genus of compositions and methods of using said compositions, wherein the compositions comprise an murine, humanized or resurfaced antibody designated

"EM164" or a fragment thereof, wherein said antibody of said fragment specifically binds to insulin-like growth factor-I receptor, and wherein said antibody or said fragment ***is an antagonist of said receptor and is devoid of agonist activity;*** and a therapeutic agent (see claims 59 and 60). Other claims are directed to an antibody that comprises at least one heavy chain variable region and at least one light chain variable region wherein the heavy chain variable region comprises the complementary determining regions comprising the amino acid sequences of SEQ ID NO:1-3 and wherein the light chain variable region comprises the complementary determining regions comprising the amino acid sequences of SEQ ID NO:4-6, an antibody comprising a heavy chain variable region comprising the amino acid sequence of SEQ ID NO:7, an antibody comprising a light chain variable region comprising the amino acid sequence of SEQ ID NO:8, an antibody comprising a light chain variable region selected from: SEQ ID NO;9, SEQ ID NO:10, SEQ ID NO:11 or SEQ ID NO:12 or an antibody comprising a heavy chain variable region comprising SEQ ID NO:13 (see e.g., claims 8, 11, 14, 15 and 16), which need not have any particular function, some of which do not need to comprise both a heavy chain and a light chain of a parent antibody. Other claims are directed to antibodies that specifically bind IGF-IR which do not need to comprise both a heavy chain and a light chain of a parent antibody that binds IGF-IR (see e.g., claims 39 and 40).

Notably, as a first point, where the claims have been amended or newly presented to not require that the recited "antibodies" bind any particular well-described antigen there can be no correlation of any particular identifying structural feature with any function of the claimed antibodies. For example, claim 8 does not recite binding to any antigen. Thus, while the claims broadly encompass a diverse genus of "antibodies", which might not bind any antigen at all or which might bind antigens other than the disclosed IGF-IR antigen, the specification fails to adequately describe these "antibodies", as a whole, because the skilled artisan could not immediately envision, recognize or distinguish as least most of its members, as the specification fails to

describe its members as sharing any particularly identifying (i.e., substantial) structural feature, which correlates with any one particularly identifying functional feature.

Accordingly, it is submitted that the specification fails to provide a representative description of at least a substantial number of the "antibodies" that are encompassed by the recited genus of antibodies which may bind any antigen. Absent such a clear and particular description of the whole of the antibodies that are encompassed by the recited genus, it appears that the specification would not adequately describe the claimed "antibodies" in a manner that would reasonably convey to the skilled artisan that Applicant had possession of that subject matter at the time the application was filed.

Secondly, in the response filed March 18, 2008 Applicant appears to be arguing at page 26 that the antibodies are adequately described because the "art references establish that prior to Applicants' filing date the state of the art of antibody production was such that a person of ordinary skill in the art would conclude, without question, that an antibody could be routinely made and used from a single CDR and that variations of an antibody wherein functional antibodies are obtained is routine in the art".

In response, this argument is not persuasive because it appears that Applicant is arguing that one of skill in the art could ***make*** antibodies from a single CDR, and as set forth in the previous office action, "it is duly noted that the written description provision of 35 U.S.C § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it".

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (CAFC 1991). See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (CAFC 1991); *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

Notably, in this case, while the claims encompass compositions comprising antibodies comprising amino acid sequences which need not bind any well-characterized antigen (see claim e.g., claim 8) and/or which need not comprise each of the 6 CDRs of a parent antibody that binds the IGF-IR antigen (see e.g., claim 11), the specification has not characterized any other **antigen** that antibodies comprising the six CDRs as set forth in claim 8 can bind and the specification has not characterized any or antibody fragment comprising **less than 6 CDRs of a parent antibody** that specifically binds the IGF-IR antigen which retains the function of binding IGF-IR antigen. Notably, while the art cited by Applicant may suggest that other antibodies comprising the recited sequences which bind other antigens or other antibodies comprising the recited sequences which bind IGF-IR antigen could be screened for could be screened for, they do not provide one of skill in the art a generic teaching as to which structures would be required from an antibody that specifically binds IGF-IR, comprising at least one heavy chain variable region and at least one light chain variable region wherein the heavy chain variable region comprises the complementary determining regions comprising the amino acid sequences of SEQ ID NO:1-3 and wherein the light chain variable region comprises the complementary determining regions comprising the amino acid sequences of SEQ ID NO:4-6 to retain such binding, so one of skill in the art would not consider such an antibody to provide representative support for antibodies that, for example, consist of a heavy chain variable region consisting of the amino acid sequence of SEQ ID NO:7 (which is encompassed by claim 8). Notably, one of skill in the art could not immediately envision, recognize or identify fragments containing less than all 6 CDRs of a parental antibody, based on the state of the art, which would retain antigen binding affinity for the original antigen and because the specification has not characterized any fragments containing less than 6 CDRs of a parental antibody which retain binding for IGF-IR antigen, one of skill in the art would not conclude that Applicant was in possession of antibodies which specifically bind IGF-IR which recite less than all 6 CDRs of the parental antibody. Notably, as set forth previously, while Gussow et al (of record) teach the general methodology for making humanized antibodies which

retain antigen binding function of the parental antibody by grafting the six CDRs from the light and heavy chain variable domains from a murine antibody into the framework of a human antibody, if only one or two of the CDRs from either the light or heavy chain variable domain were to be grafted, but not all three, the resultant antibody would not be expected to retain the binding affinity and specificity of the parent antibody. Therefore, since it is expected that all 6 CDRs need to be grafted into antibody framework regions to retain the requisite affinity and specificity of the parent antibody, antibody variants comprising less than all 6 CDRs grafted into their proper context of framework regions, i.e., are not antibodies or antigen-binding fragments thereof that contain all 6 CDRs of the parent antibody, would not be immediately envisioned or recognized by one of skill in the art as having the affinity and specificity of the parent antibody based on the instant disclosure.

Finally with respect to new claims 59[2] and 60, while the term "EM164" is not expressly defined in the specification, it is being interpreted in light of the disclosure of original claim 1, which recites that such antibodies include functional equivalents and variants of the murine antibody EM164 which can comprise mutations, deletions or insertions. Furthermore the specification discloses at page 17 that:

> "The primary amino acid and DNA sequences of antibody EM164 light and heavy chains, and of humanized versions, are disclosed herein. However, the scope of the present invention is not limited to antibodies and fragments comprising these sequences" and
>
> "The CDRs of antibody EM 164 are identified by modeling and their molecular structures have been predicted. Again, while the CDRs are important for epitope recognition, they are not essential to the antibodies and fragments of the invention".

Thus, it is apparent that the claims do not require that a murine, humanized or resurfaced "EM164" antibody comprise any particularly identifying structural feature of the EM164 antibody produced by the hybridoma deposited as ATCC-4457, nor does the specification identify these functional equivalents or variants as comprising any

[2] Since claim 59 recites an ATCC number of a hybridoma in parenthesis it is unclear whether this recitation is meant to limit the antibody to the antibody produced by the hybridoma as set forth in the below 35 USC 112, second paragraph rejection and therefore, the claim is being broadly, but reasonable interpreted to encompass "EM164" antibodies other than that produced by this hybridoma

particularly identifying structural feature of the EM164 antibody produced by the hybridoma deposited as ATCC-4457, and for this reason, one of skill in the art would not be able to immediately envision, recognize or predict which of murine, humanized or resurfaced "EM164" antibodies which specifically bind IGF-IR and are *devoid of agonist activity and are antagonists of said receptor.*

Accordingly, after careful and complete consideration of Applicant's arguments, for these reasons and for the reasons previously set forth, the specification as filed does not adequately describe the antibodies to which the claims are directed and this rejection is maintained.

14. The rejection of claims 17, 30, and 32-34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a NEW MATTER rejection.

Starting at page 26 of the response filed December 12, 2008, Applicant has traversed this ground of rejection.

In the response filed December 12, 2008, Applicant has traversed this objection and reiterated that the Office's position is contrary to 37 CFR 1.57 and that the facts in *Ex parte Maziere* support that these agents have been properly incorporated and further points to the facts in *Southern Clay Products, Inc., v. United Catalysts, Inc., 43 Fed.Appx. 379, 64 U.S.P.Q.2d 1606 (Unpublished) (No. 01-1382) (July 26, 2002)* and the holdings in *In the Matter of the APPLICATION of Raymond O. VOSS,* as supporting that the incorporation by reference is proper.

In response, while the Examiner acknowledges the holdings of *Ex parte Maziere, Southern Clay Products, Inc., v. United Catalysts, Inc., 43 Fed.Appx. 379, 64 U.S.P.Q.2d 1606 (Unpublished) (No. 01-1382) (July 26, 2002)* and the holdings in *In the*

Matter of the APPLICATION of Raymond O. VOSS pointed to by the Applicant, each case must be decided on its own facts.

As set forth by 37 CFR 1.57 (c) "Essential material" may be incorporated by reference, but only by way of an incorporation by reference to a **U.S. patent or U.S. patent application publication**, which patent or patent application publication does not itself incorporate such essential material by reference.

Accordingly, while the holdings cited by Applicant refer to "Essential material" that was incorporated by reference to a U.S. patent or U.S. patent application publication, this case differs because it incorporates non-patent literature, for example, and it is not apparent that these holdings apply in this case because "Essential material" may only be incorporated by reference to a U.S. patent or U.S. patent application publication.

Furthermore, Applicant argues that the incorporation by reference of these particular second agents is proper as Applicant expressed a clear intent to incorporate by reference the content of the publications cited in the specification and because the Applicants "call out the diverse agents used in oncology practice" as set forth in the following disclosure at page 26:

> The therapeutic agents that can be combined with EM164 for improved anti-cancer efficacy include diverse agents used in oncology practice (Reference: Cancer, Principles & Practice of Oncology, DeVita, V. T., Hellman, S., Rosenberg, S. A., 6th edition, Lippincott- Raven, Philadelphia, 2001) ...

In response, while the Examiner acknowledges that the specification generically refers to diverse anti-cancer agents used in oncology practice and incorporates all the publications identified in the specification in their entirety at page 69, Applicant's argument that the addition of these particular species to claims 17, 30, and 32-34, after the filing date of the instant application, is not new matter, is not persuasive because one of skill in the art would not have immediately envisioned that thalidomide, carmustine, pamidronate, prednisone, erythropoietin and bisohosphonate were species originally disclosed and contemplated for use in combination with the instant antibodies

based on the generic disclosure of anti-cancer agents and the disclosure of DeVita et al which is over 3000 pages. For example, while the specification sets forth that the agents are for improved anti-cancer efficacy, the claims have been amended to include erythropoietin which DeVita et al discloses is used for anemia (see page 2644), and pamidronate which DeVita et al discloses is used for bone pain (see page 2831). One of skill in the art would not consider these agents to have anti-cancer properties. Furthermore, since the genus of "agents" in this case is so broad and diverse, it is submitted that one of skill in the art would not have been led to the species thalidomide, carmustine, pamidronate, prednisone, erythropoietin and bisohosphonate with any *particularly*, and therefore, would not have identified these species of agents as part of the invention originally contemplated by the inventors. As set forth by the CCPA in *In re Seversky,* 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"). Similarly, in *In re Saunders*, 444 F.2d 599, 602-03, 170 USPQ 213, 216-17 (CCPA 1971) the CCPA held that a reference only discloses information from an incorporated reference when it "expressly incorporates a particular part" of another reference. In this case, since one of skill in the art would not have been led to the species thalidomide, carmustine, pamidronate, prednisone, erythropoietin and bisohosphonate of DeVita et al with any *particularly,* based on the application as *originally filed*, it is submitted that this clearly illustrates that such amendments have in fact introduced new concepts, thereby violating the written description requirement set forth under 35 U.S.C. §112, first paragraph.

Thus, after a careful and full consideration of Applicant's arguments, the specification lacks information to lead one of skill in the art to understand that the applicant had possession of the claimed invention at the time the instant application was filed. Therefore, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed and this rejection is maintained.

Otherwise this issue might be resolved if Applicant were to point to other disclosures in the specification, including the claims, as originally filed, which are believed to provide the necessary written support for the language of the instant claims.

15. The rejection of claims 8, 11, 14-19, 22, 24, 26, 27, 30-34, 37, 39-43, 59-60 and 62 under 35 U.S.C. 112, first paragraph, because the specification, **while being enabling for making and using** a composition comprising an antibody or antigen-binding fragment thereof that specifically binds to insulin-like growth factor-I receptor (IGF-I-R), wherein said antibody or antigen-binding fragment comprises a heavy chain variable domain comprising a CDR1 consisting of SEQ ID NO:1, a CDR2 consisting of SEQ ID NO:2, a CDR3 consisting of SEQ ID NO:3 and a light chain variable domain comprising a CDR1 consisting of SEQ ID NO:4, a CDR2 consisting of SEQ ID NO:5, a CDR3 consisting of SEQ ID NO:6, **does not reasonably provide enablement for making and using** a composition comprising (i) the full scope of the broad genus of murine, humanized and resurfaced "EM164" antibodies, the antibodies set forth in claims without any particular function and the antibodies of the claims which comprise less than the 6 CDRs as set forth above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

MPEP § 2164.01 states:

> The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

Starting at page 21 of the amendment filed March 18, 2008, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

In the traversal, at page 30 Applicant has incorporated their response regarding the state of the art set forth in their response to the written description rejection and appears to be arguing at page 26 that the antibodies are enabled because the "art references establish that prior to Applicants' filing date the state of the art of antibody production was such that a person of ordinary skill in the art would conclude, without question, that an antibody could be routinely made and used from a single CDR and that variations of an antibody wherein functional antibodies are obtained is routine in the art".

In response, this argument is not found persuasive because the Examiner respectfully disagrees that it was routine or conventional in the art to make antibodies comprising less than all 6 CDRs that are functionally equivalent to a parent antibody. While Applicant has identified art suggesting that for particular antibodies specific for some particular epitopes on some particular antigens, that functionally active peptides comprising less than all 6 CDRs of an antibody in their proper context of antibody framework regions might be obtained, it has not been established that it is conventional or routine in the art to be able to make such peptides for *any* given parental antibody and the instant specification does not provide any specific, non-general guidance which would allow one of skill in the art to make and use the full scope of the claimed antibodies.

Additionally, this argument is not found persuasive because although one could potentially screen antibody libraries that comprise the recited sequences with random CDRs or randomly mutated CDRs at the other CDR positions to identify those antibodies that comprise functional equivalents of the CDRs of the parental antibody the specifically binds IGF-IR, the artisan cannot predict whether any given CDR will function in a manner complementary to a corresponding CDR present in the parental antibody. The functionality of candidate CDRs can only be determined empirically. Because *it cannot be known beforehand* whether in fact there are functional equivalents of the

CDRs of the parental antibody that specifically binds IGF-IR, which can be used to produce the claimed antibodies with less than all 6 of the CDRs present in the parental antibody which specifically binds IGF-IR, it is submitted that the production of the claimed invention by the artisan would fall into the realm of undue and/or unreasonable experimentation, despite the routine nature of the screening process itself by which such functional equivalents might, if such exist, be identified. Accordingly undue and unreasonable experimentation would be required to determine which CDRs could predictably be altered or substituted while retaining IGF-IR antigen binding.

Furthermore, while the claims recite comprising language, claim 8 encompasses antibodies that, for example, consist of a heavy chain variable region consisting of the amino acid sequence of SEQ ID NO:7, and it is highly unpredictable whether such antibodies could be used because as previously set forth as evidenced by Gussow et al (of record), for example, generally all 6 CDRs of a parental antibody are required for antigen binding. In this case, the specification presents no specific, non-general guidance that an antibody consisting of a heavy chain variable region consisting of the amino acid sequence of SEQ ID NO:7 would be able to bind IGF-IR and therefore, it is maintained that one of skill in the art would be subject to undue and unreasonable experimentation to use the full scope of the claimed antibodies.

Then, wherein the claims are not limited to compositions comprising antibodies or binding fragments thereof that specifically bind to one well-characterized antigen, but entirely lack antigen-binding function, one of skill in the art would be subject to undue and unreasonable experimentation to make and use the claimed products and methods reasonably commensurate in scope with the claims. For example, one of skill in the art would be subject to undue experimentation to make antibodies with the recited sequences which bind to an antigen other than the disclosed IGF-IR antigen. In this case, the specification does not provide any specific, non-general guidance as to how antibodies comprising these sequences might be made and used to bind any other antigen. For these reasons, one of skill in the art would be subject to undue

experimentation to make and use antibodies commensurate to the full scope of the claimed invention.

Finally with respect to new claims 59[3] and 60, while the term "EM164" is not expressly defined in the specification, it is being interpreted in light of the disclosure of original claim 1, which recites that such antibodies include functional equivalents and variants of the murine antibody EM164 which can comprise mutations, deletions or insertions. Furthermore the specification discloses at page 17 that:

> "The primary amino acid and DNA sequences of antibody EM164 light and heavy chains, and of humanized versions, are disclosed herein. However, the scope of the present invention is not limited to antibodies and fragments comprising these sequences" and
>
> "The CDRs of antibody EM 164 are identified by modeling and their molecular structures have been predicted. Again, while the CDRs are important for epitope recognition, they are not essential to the antibodies and fragments of the invention".

As set forth in the previous action, the specification has not provided any specific, non-general guidance as to how to make such functional equivalents or variants of antibody EM164 that are devoid of agonist activity.

Applicant is reminded that reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

In deciding *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970), the Court indicated the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. "Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001, 1005 (CA FC 1997).

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[3] Since claim 59 recites an ATCC number of a hybridoma in parenthesis it is unclear whether this recitation is meant to limit the antibody to the antibody produced by the hybridoma as set forth in the below 35 USC 112, second paragraph rejection and therefore, the claim is being broadly, but reasonable interpreted to encompass "EM164" antibodies other than that produced by this hybridoma

Thus, the overly broad scope of the claims would merely serve as an invitation to one skilled in the art to identify other antibodies that are encompassed by the claims; yet, defining a substance by its principal biological activity amounts to an alleged conception having no more specificity than that of a wish to know the identity of any material with that biological property. See *Colbert v. Lofdahl*, 21 USPQ2d 1068, 1071 (BPAI 1991).

In conclusion, upon careful and full consideration of Applicant's arguments and the factors used to determine whether undue experimentation is required, in accordance with the Federal Circuit decision of *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the amount of guidance, direction, and exemplification disclosed in the specification, as filed, is not deemed sufficient to have enabled the skilled artisan to use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation, and this rejection is being maintained.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. The rejection of claims 8, 11, 14-19, 22, 24, 26, 27, 30-34, 37-44, 46-51, 59-63 and 67-69 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of US Patent 7,538,195[4] in view of Teicher et al, is maintained for the reasons of record, as explained in the Office action mailed October 18, 2006.

In the amendment filed December 12, 2008, Applicant does not appear to address the double patenting rejection and the rejection will be maintained until it is appropriately resolved.

New Grounds of Objection

Claims

18. Claims 68 and 69 are objected to as being drawn in the alternative to antibodies comprising non-elected sequences, i.e., SEQ ID NO: 83, 84, 85, 86 and 88.

19. Claim 68 is also objected to for reciting "fro". Appropriate correction is required.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

20. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

21. Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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[4] This rejection previously recited copending Application No. 10/170,390 which has since issued as US Patent 7,538,195 so the rejection is no longer provisional

Claim 59 is indefinite for reciting murine antibody EM164 followed by an ATCC deposit number in parenthesis. As such, it is submitted that it is unclear if this parenthetical reference is meant to further limit the claim, or if the reference is merely exemplary of a hybridoma that produces an "EM164" antibody. Is the "EM164" antibody of the claim produced by the hybridoma or is the antibody produced by the hybridoma merely exemplary of the "EM164" antibodies of the claim? Therefore the claim fails to delineate the metes and bounds of the subject matter that Applicant regards as the invention with the requisite clarity and particularity to permit the skilled artisan to know or determine infringing subject matter. Amending the claims to recite "the murine antibody EM164 produced by the hybridoma deposited as ATCC number PTA-4457", for example, would obviate this rejection.

For this reason, it is submitted that the claim fails to delineate the metes and bounds of the subject matter that Applicant regards as the invention with the requisite clarity and particularity to permit the skilled artisan to know or determine infringing subject matter.

Double Patenting

22. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

23. Claim 45 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 8 of US Patent 7,538,195.

In this case, claim 45 recites: A pharmaceutical composition comprising the antibody or antibody fragment of claim 38 and a pharmaceutically acceptable carrier, and the antibody or antibody fragment of claim 38 is defined as an isolated antibody or fragment thereof, wherein said antibody or said fragment comprises at least one heavy chain variable region and at least one light chain variable region, wherein said heavy chain variable region comprises three complementarity-determining regions comprising the amino acid sequences of SEQ ID NOS: 1-3, and wherein said light chain variable region comprises three complementarity-determining regions comprising the amino acid sequences of SEQ ID NOS:4-6, and wherein said antibody or said fragment specifically binds to IGF-IR.

Then in US Patent 7,538,195, claim 8 recites: A pharmaceutical composition comprising the antibody or antibody fragment of claim 1 and a pharmaceutically acceptable carrier, and the antibody or antibody fragment of claim 1 is defined as an isolated antibody or fragment thereof that specifically binds to IGF-IR, comprising at least one heavy chain variable region and at least one light chain variable region, wherein said heavy chain variable region comprises three complementarity-determining regions comprising the amino acid sequences of SEQ ID NOS:1-3, and wherein said light chain variable region comprises three complementarity-determining regions comprising the amino acid sequences of SEQ ID NOS:4-6.

Since the sequences are 100% identical the claims are drawn to pharmaceutical compositions of identical scope. Notably, instant claim 45 only refers to the antibody of claim 38, **not** the composition of claim 38, so it does not require the therapeutic agent of claim 38.

Conclusion

24. No claim is allowed.

25. Applicant's amendment necessitated the new ground(s) of objection and rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

26. As set forth in the precious office action, the deposit requirements set forth in 37 CFR 1.801-1.809 have been met for the hybridoma cell line EM164 deposited under ATCC Deposit No. PTA-4457.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:30 PM, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
June 6, 2009